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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------|----------------------|---------------------|------------------|
| 09/700,259 | 10/30/2001 | Geoffrey P. Margison | PM 275388 | 3434 |
| 909 | 7590 | 10/07/2003 | EXAMINER | |
| PILLSBURY WINTHROP, LLP | | | ANGELL, JON E | |
| P.O. BOX 10500 | | | ART UNIT | |
| MCLEAN, VA 22102 | | | PAPER NUMBER | |
| | | | 1635 | |

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/700,259 | MARGISON ET AL. | |
| | Examiner | Art Unit | |
| | J. Eric Angell | 1635 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 51-53 have been cancelled. Claims 1-49 are currently pending and are addressed herein.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-48, drawn to vector material comprising (a) a tumor cell sensitizing gene(s), (b) a sensitizing gene expression regulatory system, (c) at least one control gene, and (d) a control gene regulatory system.

Group II, claim(s) 49, drawn to a method of treating cancer using the vector material of group I.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: in order for a technical feature to be special it must be novel. In the instant case, Groups I and II are linked by the vector material (the technical feature). However, this technical feature is not novel, as evidenced by the teachings of Gu (Science 1994, Vol. 265, pages 103-106), cited as an "X" reference in the international search report. Since the vector material is not novel, the technical feature linking the claims is not special.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Art Unit: 1635

The species of prodrug activating enzymes are as follows:

HSV thymidine kinase,
nitroreductase,
cytosine deaminase,
cytochrome p450
2E1
cytochrome D450 2DV1

The species of immune-response modifying agents are as follows:

GM-CSF,
IFN-alpha,
IFN-beta,
IFN-gamma,
1L-1beta,
IL-2,
IL-4,
IL-6,
IL-8,
IL-10,
IL-12,
IL-15,
TNF-alpha

The species of expression controlling agents are as follows:

electromagnetic radiation,
application of heat
application of cooling,
application of a magnetic field,
application of an electric field,
an exogenous chemical inducing agent,
radiation in the form of sub-atomic particles

The species of antitumor drugs are as follows:

Temozolomide, Dacarbazine, Streptozotocin, Procarbazine, Carmustine,
Semustine, Lomustine, Fotemustine, Busulphan, Treosulphane,
Mechlorethamine, Cyclophosphamide, Iphosphamide, Chlorambucil,
Melphalan, ethyleneimines, triethylene melamine, hexamethylmelamine,

Art Unit: 1635

TEPA and thio-TEPA, dibromomannitol and dibromodulcitol, hydroxyurea, Methotrexate, azaserine Azathioprin, s-azacytidine, s-fluorouracil, cytosine arabinoside, 6-mercaptopurine, Allopurinol 6-thioguanine, deoxycoformycin, Tiazofurin, Acivicin, Pyrazofurin and p-aminolaevulinic acid, plant alkaloids such as Vinblastine, Vincristine and Vindesine, Etoposide and Teniposide, antitumour antibiotics such as Doxorubicin, Daunorubicin, Actinomycin, Bleomycins, Mytomycin, Mythramycin, Mitozantrone hormones such as estrogen and progesterone.

Applicant is required, in reply to this action, to elect a single species from each group of species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1-48.

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species are not novel, therefore there is not special technical feature linking the different species.

Art Unit: 1635

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

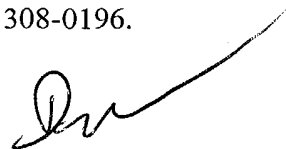
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell
Art Unit 1635



DAVE T. NGUYEN
PRIMARY EXAMINER